

## REMARKS

The present invention pertains to a method for treating neuropathically-induced negative sensory phenomena (numbness of the skin) by application of a local anesthetic at the site of the numbness. The method involves topically applying a local anesthetic to the skin at or near the site of the numbness.

The claims of the present invention had previously been rejected under 35 USC § 103(a) as being unpatentable over Katz et al. (US 5,028,435) in view of Goodman and Gilman's (The Pharmacological Basic of Therapeutics). After filing a Notice of Appeal, the Patent Office has withdrawn its rejection under 35 USC § 103(a) and instead issued a rejection under 35 USC § 112. This rejection is respectfully traversed. The Action recites the Wands factors and takes the position that one of ordinary skill in the art could not practice the invention without undue experimentation. It should be noted that this is inconsistent with the previous position taken for the same claims, i.e. that the claimed invention would be obvious to one of ordinary skill in the art.

Working through the Wands factors, the first is the "nature of the invention:"

The present invention is directed to a method of treating neuropathically-induced negative sensory phenomena (i.e. numbness) by applying an anesthetic topically to the skin. The identification of the disease state is obviously within the skill of one skilled in the art. Identifying an area of numbness on a patient is as simple as palpating the area and obtaining feedback from the patient, or direct stimulation with a needle or hot or cold stimulus. Clearly one of ordinary skill in the art would have no difficulty in identifying the condition which this invention is intended to treat.

(2) The state of the prior art:

The Examiner admits that, "the state of the prior art with respect to treating neuropathically-induced negative sensory phenomena (i.e. numbness) comprising applying an anesthetic topically to the skin is not known." While it is known to use benzoic acid derivative anesthetics as local anesthetics, anesthetics are intended to cause numbness and not to relieve numbness. The Examiner also states, "there is no disclosure in the art to teach using benzoic acid derivatives to treat numbness." Applicant disagrees with this statement. Escobar et al ("Teres Minor; Source of Symptoms Resembling Ulnar Neuropathy or C8 Radiculopathy") shows relief of tingling and numbness in the fourth and fifth fingers by injection of lidocaine at a trigger point in the Teres Minor. However Escobar fails to show relief of numbness by the topical application of a benzoic acid derivative near the focus of the numbness.

(3) The relative skill of those in the art:

This invention is intended to be used by physicians and skilled researchers. The skill in this art is therefore high--represented by users who have had significant education in the field of medicine.

(4) The predictability or unpredictability of the art:

The Action states that, “art pertaining to treating neuropathically-induced negative sensory phenomena (i.e. numbness) is highly unpredictable. It has not been shown in the art that benzoic acid derivatives can be used to treat numbness.” The Examiner has introduced no evidence to unpredictability in this art. Further, as stated above, Applicants disagree that it has not been shown in the art that benzoic acid derivatives can be used to treat numbness.

(5) The breath of the claims:

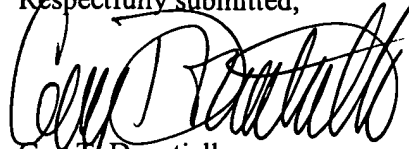
The Action states, “the claims are broad with respect to anesthetics that can be applied topically.” While claim 1 recites any anesthetic, claim 2 recites that the anesthetic is a benzoic acid derivative, claim 3 specifies fourteen specific benzoic acid derivatives, and claim 4 further limits the benzoic acid derivative to lidocaine. It can hardly be said that all of the claims are broad with respect to anesthetics that can be applied topically. If the Examiner believes that there is undue breath in one or more of the claims, the Examiner should also consider those claims which are specific in terms of the benzoic acid derivative claimed.

(6) The amount of direction or guidance presented:

The Action states, “the specification does not provide guidance to the skilled artisan as to use a local anesthetic (which causes numbness) to treat neuropathically-induced negative sensory phenomena (i.e. numbness). The specification discloses that lidocaine can be used to reduce neuropathically-induced negative sensory phenomena (i.e. numbness).” These two sentences are inconsistent. Lidocaine is a local anesthetic. As admitted by the Examiner, the specification discloses the use of lidocaine to reduce neuropathically-induced negative sensory phenomena and thus provides guidance to the skilled artisan regarding the use of a local anesthetic (lidocaine) to treat neuropathically-induced negative sensory phenomena. The Examiner admits as much. The Examiner then states “the specification does not disclose how (i.e. the mode of action) a local anesthetic can be used to treat neuropathically-induced negative sensory phenomena (i.e. numbness).” As far as Applicants are aware, there is no requirement in the patent law that the mode of action of a pharmaceutical be detailed in an application. It has never been required that one understands or be able to explain how a pharmaceutical works. If the Examiner intends to pursue this requirement it is respectfully requested that the Examiner support this requirement with appropriate case law. Accordingly, Applicant believes that the claims as presently presented are patentable and respectfully request early and favorable notification to that effect.

If the Examiner has any questions regarding the present application or present claims, it is respectfully requested that the Examiner contact Applicant's attorney at the telephone number set forth below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Guy T. Donatiello", written over the typed name.

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